

Serial No. 10/725,159

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Group Art Unit: 1615
ERNING XIA et al. : Examiner: BETHANY P. BARHAM
Serial No. 10/725,159
Filed: December 1, 2003
For: GENTLE AND ENHANCED
PRESERVATIVE SYSTEMS
Attorney Docket No. P03366

REPLY BRIEF

HONORABLE COMMISSIONER OF PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with 37 C.F.R. § 41.41, Appellants are submitting the Reply Brief shown below in response to the Examiner's Answer to Appellants' Brief, within two months from the date of the Examiner's Answer.

Response to The Examiner's Answer

1. The Examiner's Statement That Appellants Argue Against the References Individually Is Not Supported by the Record.

Throughout the response to the final rejection and the appeal brief, Appellants consistently argue that the combination of Hu and Sugiura does not teach or suggest the provision of a combination of glucose or α -methyl gluco-pyranoside and polyquaternium-10 for preservation of solution. Each of Hu and Sugiura is deficient in one non-overlapping limitation of each the claims. Therefore, it follows logically that a combination of Hu and Sugiura cannot have all of the limitations of each of the claims.

2. The Examiner's Statement That "As Long As Motivation Exists To Combine The Elements, The Problem to Be Solved Does Not Have to Involve The Same Reason for Imparting Preservative Efficacy to a Solution" Is an Erroneous Understanding of the Patent Laws.

"The determination of obviousness is made with respect to the subject matter as a whole, not separate pieces of the claim." *Sanofi-Synthelabo v. Apotex, Inc.* (Fed. Cir., Dec. 12, 2008, slip op. at pp 16-17) (citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727,1734 (2007); *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1448 (Fed. Cir. 1984)). All claim limitations must be considered. "All words in a claim must be considered in judging the patentability of that claim against the prior art." MPEP § 2143.03 (8th ed., Rev. 6, Sept. 2007) (quoting *In re Wilson*, 424 F.2d 1382, 1385 (C.C.P.A. 1970)).

Moreover, it is not required for unobviousness of the method-of-use claims that the materials be patentable. *In re Mancy*, 182 U.S.P.Q. 303, 306 (C.C.P.A. 1974).

The present claims recite a method of imparting a preservative efficacy to a contact lens solution, the method comprising providing a preserving agent that comprises a saccharide selected from the group consisting of glucose and α -methyl pyranoside in their D or L forms in combination with a polyquaternium-10 cationic polysaccharide.

The '133 Patent mentions generally mono or disaccharides as wetting agents (column 7, lines 20-21) while the '606 Patent mentions wetting agents as diverse and unrelated as purified water, distilled water, salt solutions, buffers, non-ionic surfactants (such as block copolymers of ethylene oxide and propylene glycol), castor oil, glycerin fatty acid esters (column 9, line 41 to column 10, line 2). Where in the combination of these two patents is the teaching or suggestion of using glucose or α -methyl pyranoside in their D or L forms in combination with a polyquaternium-10 cationic polysaccharide to impart preservative efficacy to a solution? The Examiner has not put forth factual or scientific reasoning that makes the leap from a disclosure of wetting agents as diverse and unrelated as purified water, buffers, non-ionic surfactants, and mono- or disaccharides to the use of glucose or α -methyl pyranoside in their D or L forms in combination with a polyquaternium-10 cationic polysaccharide to impart preservative efficacy to a solution, as inventively discovered by the Appellants. (The Examiner must provide reasoned, fact-based

Serial No. 10/725,159

explanation supported by the evidence of record, or scientific reasoning, to establish the reasonableness of the examiner's belief. *Ex parte Whalen* (BPAI, July 23, 2008), (Slip op. at pages 8, 12, and 13, quoting *Ex parte Skinner*, 2 U.S.P.Q.2d 1788, 1789 (BPAI 1986)). Thus, the Examiner has not made out a case of obviousness.

In addition, the Appellants respectfully traverse the Examiner's citation of quaternary ammonium compounds of US Patent 6,916,958 as being applicable to the present claims because none of the compounds of the '958 Patent is a polyquaternium-10 cationic polysaccharide. Again, the Examiner has not put forth any factual basis supported by scientific reasoning for her opinion that made the leap from biquanide derivatives (compounds containing the linear group -NH-C(NH)-NH-C(NH)-NR-) of the '958 Patent to the entirely different polyquaternium-10 cationic polysaccharide (containing sugar rings) of the present claims.

3. The Examiner's Statement That "Appellants Have Not Provided a Meaningful Definition of 'Effective Amount' or 'Solution Preservation' Is Not Supported by the Record.

"It is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (quoting *U.S. v. Adams*, 383 U.S. 39, 49 (1966)). The Examiner must determine the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." MPEP § 2111 (8th ed., Rev. 6, Sept. 2007) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005)).

The preservative efficacy of a material is defined very explicitly in paragraph 0029 of the specification. The testing is specified as conforming to the ISO/FDA microbial preservative efficacy testing (paragraph 0031), which is known by one ordinary skill in the art of microbial testing. Therefore, the Examiner cannot have any reason to object to the claim language when reading the claims in view of the specification.

4. The Examiner's Statement That The '133 Patent's Teaching of Prevention of "The Growth of Lipids, Proteins, And Other Products"

Serial No. 10/725,159

Would Somehow Inform The Presently Claimed Prevention of Growth of Microorganisms Does Not Make Scientific Sense And Is Not Supported by Factual and Scientific Reasoning.

The Appellants respectfully submit that lipids, proteins (and other inanimate products) do not grow, as the Examiner asserted. They are deposited on the lenses as the cited art discusses.

Moreover, the Examiner has not put forth adequately any factual basis and scientific reasoning for how the prior art's prevention of deposition of inanimate lipids or proteins on contact lenses suggests the claimed prevention of growth of living microorganisms (including bacteria and fungi).

For the reasons set forth above, Appellants respectfully submit that claims 4, 7, 9-12, 20 and 21 are patentable and should be allowed. Appellants respectfully request that the Honorable Board of Patent Appeals and Interferences reverse the Examiner's final rejection and hold claims 4, 7, 9-12, 20 and 21 allowable.

Respectfully submitted

A handwritten signature in black ink, appearing to read 'Toan P. Vo', written over a horizontal line.

Toan P. Vo, Ph.D.
Attorney for the Appellants
Registration No. 43,225
(585)338-8071

Bausch & Lomb Incorporated
One Bausch & Lomb Place
Rochester, New York 14604
January 12, 2009